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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/790,268 | 03/01/2004 | Leo J. Romanczyk JR. | 1010/100US3 | 3127 |

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| EXAMINER | |
|---|---|
| NUTTER, NATHAN M | |
| ART UNIT | PAPER NUMBER |
| 1711 | |

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/790,268 | ROMANCZYK ET AL. | |
| | Examiner | Art Unit | |
| | Nathan M. Nutter | 1711 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *25 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *27-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0405*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Amendment*

The rejection of claims 27-78 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is hereby expressly withdrawn.

The rejection of claims 27-78 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is hereby expressly withdrawn.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-47, 55-61 and 67-75 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Tempesta.

The reference to Tempesta teaches the use of proanthocyanidine polymers that may comprise the identical "flavenoid 3-ol units linked together through common C(4)-(6) *(sic)* and/or C(4)-C(8)," as herein recited, at the paragraph bridging column 1 to column 2. At column 1 (lines 13-20) the reference teaches the "proanthocyanidin polymers, having 2 to 30 flavenoid units in treating respiratory virus infections," i.e. used in a "therapeutically effective" amount, as recited in instant claims 33, 40, 47, 61 and 73. Note the structures at columns 5-8. The Abstract teaches the use of isolated and synthesized forms of the compounds. The reference teaches the topical administration,

intravenous administration, oral and nasal administrations at column 9 (lines 15-18) and the vaginal administration at column 38 (line 45) to column 39 (line 18).

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 27-61 and 67-77 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,747,059. Although the conflicting claims are not identical, they are not patentably distinct from each other because the administration of the oligomers of procyanidin of the instant claims is within the recitations of the patented claims wherein the oligomers are of the same chemical structures having "interflavin linkages 4⇐6 and/or 4⇐8." It is irrelevant whether the compounds are isolated or synthesized, the reference teaches both forms, since the composition is identical regardless. Further, the patent claims administration broadly. Any form of administration, oral, rectal, intravenous, vaginal, etc. would be an obvious variant, since "administration," as recited in the claims, includes each of these.

Claims 27-61 and 67-77 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-25 of U.S. Patent No. 6,524,630. Although the conflicting claims are not identical, they are not patentably distinct from each other because the administration of the procyanidin oligomers recited in the instant claims is within the recitations of the patented claims wherein the oligomers may be of the same chemical structures. It is irrelevant whether the compounds are isolated or synthesized, the reference teaches both forms, since the composition is identical regardless. Further, the patent claims administration broadly. Any form of administration, oral, rectal, intravenous, vaginal, etc. would be an obvious variant, since "administration," as recited in the claims, includes each of these.

Claims 27-78 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 5,712,305. Although the conflicting claims are not identical, they are not patentably distinct from each other because the administration of the procyanidin oligomers recited in the instant claims is within the recitations of the patented claims wherein the oligomers may be of the same chemical structures. It is irrelevant whether the compounds are isolated or synthesized, the reference teaches both forms, since the composition is identical regardless. Further, the patent claims administration broadly. Any form of administration, oral, rectal, intravenous, vaginal, etc. would be an obvious variant, since "administration," as recited in the claims, includes each of these. Since the reference is drawn to the use of an antineoplastic agent, the use of other known agents for this purpose would also be an obvious variant.

***Response to Arguments***

Applicant's arguments filed 25 April 2005 have been fully considered but they are not persuasive.

The reference to Tempesta, which teaches clearly the antiviral activity in the Abstract, teaches the use of proanthocyanidins, which broadly embraces and includes the procyanidins, and particularly those disclosed at the paragraph bridging column 1 to column 2. Since a reference is taken for the entirety of its teachings, to pick isolated teachings of a reference which lie outside of the scope of the claims in order to assert a difference would be improper. Applicants allege that the reference fails to "explicitly disclose pharmaceutical compositions comprising the *subgenus* of compounds recited in claims 27-30, 33-37, 40-44, 47, 55-58, 61, 67-70, and 73-75 or the *species* recited in claims 31, 32, 38, 39, 45, 46, 59, 60, 71 and 72. Under the U.S. Patent Law, a disclosure of a genus which does not explicitly disclose a subgenus or a species does not anticipate the subgenus or the species unless the genus is small ." However, applicants ignore the section pointed out in the Office Action. Further, to bolster their allegation, applicants go on to assert that the

"compounds of Tempesta are polymers represented by the structural formulas I-IV, (cols. 6-8), wherein each monomeric unit contains any one of many hydroxyl (OH) group combinations, i.e., (1) the number of OH groups on the A ring may be 1-3, on the B ring may be 1-3, and on the C ring may be 0 or 1; and (2) the OH groups may be located on various carbon (C) atoms of the A, B, and C rings. Adding further to the diversity, the monomeric units in Tempesta's pro*antho*cyanidins may be connected via single or double linkages (col. 9, lines 12-13) and may be derivatized, for example, esters, ether and oxonium derivatives are included (col. 6, lines 22-25)."

This is not deemed to be persuasive in the absence of acknowledgement as to what the reference teaches.

The rejections of the claims under the judicially-created doctrine of obviousness-type double patenting over patents 6,747,059, 6,524,630 and 5,712,305 are being maintained. It is not relevant as to the filing dates of either reference since the questions of ownership may arise later. With regards the rejection over USPN 6,524,630, the instant claims do not exclude the acetyl salicylic acid component. Regardless, removal of that component to remove its effects would be obvious to a practitioner. A timely filed Terminal disclaimer is required to overcome the reasons for the rejections as set out above.

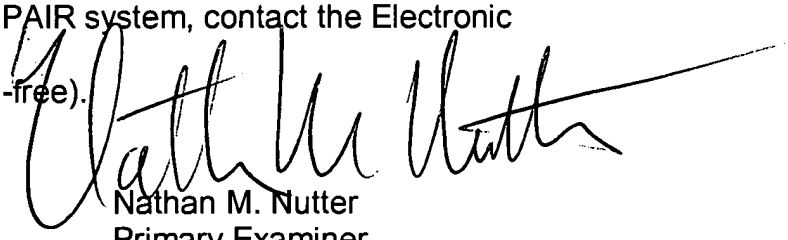
**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan M. Nutter whose telephone number is 571-272-1076. The examiner can normally be reached on 9:30 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James J. Seidleck can be reached on 571-272-1078. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nathan M. Nutter
Primary Examiner
Art Unit 1711

nmn

13 June 2005